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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/442,542	11/18/1999	LONNIE D SHEA	4100.002000	6026

23720 7590 06/10/2003

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KAUSHAL, SUMESH

ART UNIT	PAPER NUMBER
1636	24

DATE MAILED: 06/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/442,542	SHEA ET AL.	
	Examiner	Art Unit	
	Sumesh Kaushal Ph.D.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 26 March 2003.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-68, 102-117 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 48 and 54-65 is/are allowed.
- 6) Claim(s) 1-12,19-47,49-53,66-68 and 102-117 is/are rejected.
- 7) Claim(s) 13-18 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>23,22,17</u> . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Applicant's response filed on 03/26/03 has been acknowledged.

Claims 104-117 are newly filed.

Claims 1-7, 13-15, 41-43, 45-51, 66, 68, 10 and 103 are amended.

Claims 1-68 and 102-117 are pending and are examined in this office action.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

► *Applicants are advised to follow Amendment Practice under revised 37 CFR §1.121 (<http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/revamdtprac.htm>). Each amendment document that includes a change to an existing claim, or submission of a new claim, must include a complete listing of all claims in the application. After each claim number, the status must be indicated in a parenthetical expression, and the text of each claim under examination (with markings to show current changes) must be presented. The listing will serve to replace all prior versions of the claims in the application.*

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-12, 19-47, 49-53, 66-68, 102-117 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mikos et al (US 5,514,378, 1996) and Grinstaff (5,639473, 1997) and further in view of Mineau-Hanschke (US 5,965,125 1999; filed 1995).

Mikos teaches a biocompatible porous membrane structure comprising a synthetic polymer selected from group consisting of poly(alpha esters), polyanhydrides, polyorthoesters, poly(vinyl alcohol), and ethylene vinyl acetate. The cited art further teaches the use of biodegradable polymers including poly(lactic acid), poly(DL-lactic -co-glycolic acid) (PLGA). See col.3, lines 6-25; col. 23-24. The cited art further teaches making a porous polymer leaching out of a particulate from the polymer (col.6 line 41, col.7 example-1). The cited art further teaches preparation of multiplayer laminates of porous membrane using poly(L-lactic acid) and copolymers of poly(DL-lactic-co-glycolic acid) see col.14 example-2). The cited art further teaches a porous structural matrix comprising chondrocytes (col. 14, line 63-). However the cited art does not teach or suggest the incorporation of a nucleic acid segment into the structural matrix.

Grinstaff teaches biocompatible polymer composition for in-vivo gene delivery comprising a nucleic acid construct (col. 39 example-13). The cited art teaches that the biocompatible material comprises a naturally occurring polymer or a synthetic polymer or combination thereof (col.54 lines 13-18). The cited art teaches that the nucleic acid constructs are selected from IGF-1 encoding sequence, Factor VIII encoding sequence, Factor IX encoding sequence, or antisense nucleotide sequences (col. 55 lines 16-35). The cited art teaches the selection of a synthetic polymer from polyalkylene glycols, polyvinyl alcohol, polyhydroxyethyl methacrylate, polyacrylic acid, polyethyloxazoline, polyacrylamide, or polyvinyl pyrrolidinone and natural polymer selected from starch, cellulose, dextrans, alginates, chitosan, pectin, or hyaluronic acid (col.54, lines 37-67, col. 55, lines 1-18).

Mineau-Hanschke teaches a hybrid matrix composition comprising an insoluble collagen fibrils plurality of genetically engineered cells embedded in the matrix (abstract, col.1 line 55, col.19 line 25). The cited art further teaches matrix further comprises a non-collagen fibers comprising a material selected from the group consisting of nylon, dacron, polytetrafluoroethylene, polyglycolic acid, polylactic/polyglycolic acid mixture, polystyrene, polyvinylchloride copolymer, cat gut, cotton, linen, polyester and silk (col. 20 lines 56-61). The

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cited art further teaches the genetically engineered cells that contain an exogenous gene encoding a useful polypeptide, wherein the exogenous DNA encodes one or more medically useful polypeptides such as an *enzyme, hormone, cytokine, colony stimulating factor, angiogenesis factor, vaccine antigen, antibody, clotting factor, regulatory protein, transcription factor, receptor, or structural protein*. Examples of such polypeptides include *human growth hormone (hGH), Factor VIII, Factor IX, erythropoietin (EPO), albumin, hemoglobin, alpha-1 antitrypsin, calcitonin, glucocerebrosidase, low density lipoprotein (LDL) receptor, IL-2 receptor, globins, immunoglobulins, catalytic antibodies, the interleukins, insulin, insulin-like growth factor 1 (IGF-1), parathyroid hormone (PTH), leptin, the interferons, nerve growth factors, basic fibroblast growth factor (bFGF), acidic FGF (aFGF), epidermal growth factor (EGF), endothelial cell growth factor, platelet derived growth factor (PDGF), transforming growth factors, endothelial cell stimulating angiogenesis factor (ESAF), angiogenin, tissue plasminogen activator (t-PA), granulocyte colony stimulating factor (G-CSF), and granulocyte-macrophage colony stimulating factor (GM-CSF)*. see Col. 2 lines 46-67, col.3 line 1-6, col.18 line 10).

Thus it would have been obvious to one ordinary skill in the art at the time of filing to modify the porous matrix of Mikos by incorporating nucleic acid sequences as taught by Grinstaff. One would have been motivated to make a synthetic porous polymer comprising cells and nucleic acid molecules because incorporation of DNA molecules in the matrix structure would genetically alter the host cells at the transplantation site. One would have a reasonable expectation of success in doing so because controlling the porosity of a matrix structure and transfection of host cells around the transplantation site via DNA or RNA construct is considered routine in the art. In addition replacing a nucleic acid segment with another is an obvious variation since the cited art of record clearly teaches use of medically useful polypeptides encoded by gene of interest. Thus the invention as claimed is *prima facie* obvious in view of cited prior art of record.

In addition the scope of invention as claimed encompasses a product-by-process, wherein the invention as claimed fail to recite any structural limitation that distinguishes the claimed product over the prior art of record. Given the broadest reasonable interpretation the composition as claimed merely reads upon **a porous gel containing a nucleic acid segment**, which has been clearly anticipated by the cited art of record. In the instant case the combined teaching of cited

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art clearly suggest the composition as claimed, since the art teaches the use of synthetic polymers in making a porous matrix comprising cells and nucleic acid segments.

Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps (see MPEP §2113). Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Even though the pores of the composition as claimed in the instant application is made by gas foaming and leachable particulate material the final porous structure as claimed is not distinguishable from the structure as taught by the cited prior art of record. Thus the combined teaching of cited art of record clearly suggested invention as claimed.

Conclusion

Claims 1-12, 19-47, 49-53, 66-68, 102-117 are rejected.

Claims 48, 54-65 are allowable.

Claims 13-18, are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten independent form including all of the limitation of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal Ph.D. whose telephone number is 703-305-6838. The examiner can normally be reached on Mon-Fri. from 9AM-5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yucel Irem Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-8724 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

S. Kaushal
Patent examiner

[Signature]
JEFFREY FREDMAN
PRIMARY EXAMINER